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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,999	09/25/2003	Andreas Meiser	WWELL82.001AUS	4527

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EXAMINER

WIEST, PHILIP R

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/670,999

Applicant(s)

MEISER ET AL.

Examiner

Phil Wiest

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 18-25 and 27-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/27/03, 2/13/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Claims 1-17 and 26 in the reply filed on October 16, 2006 is acknowledged.

Claims 18-25 and 27-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 17, 2006.

Claim Objections

2. Claim 10 is objected to because of the following informalities:

Claim 10 recites the limitation "the control unit" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim. A control unit is not disclosed in Claim 10 or any claim from which it depends. Examiner suggests that "the control unit" in Claim 10 be replaced with "a control unit." Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3761

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-4, 6, 8-10, 16, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Hole et al. (US 2004/0081580).

1. With respect to Claim 1-4 and 6, Hole et al. disclose a device 10 comprising a pump arrangement 4, a venous catheter 50 and arterial catheter (14 and 16) for maintaining artificial circulation, a first means 7 for feeding an analysis gas into the artificial circulation, and a second means 140 capable of monitoring whether a blood exchange takes place between the artificial circulation and the systemic circulation of the body 2. Hole et al. further disclose that the first means comprise an oxygenator 32 and an analysis gas delivery line 9 capable of delivering analysis gas into said oxygenator 32, and that the second means comprise at least one gas sensor 140 for the analysis gas, as per Claims 2, 3, and 4. Said at least one sensor 140 is arranged in the artificial circulation, as per Claim 6. See Figures 1 and 9.

2. With respect to Claims 8 and 10, Hole et al. disclose a flow control valve/pressure regulator 8 on analysis gas delivery line 9. In order to regulate pressure and control flow, said flow control valve/pressure regulator 8 must be able to sense the amount of gas in the line. Therefore, the flow control valve/pressure regulator 8 is capable of acting as a gas sensor. Furthermore, with respect to Claim 10, it is inherent that if flow is being controlled, the flow control valve/pressure regulator must be connected to the control unit 1 in some way.

Art Unit: 3761

3. With respect to Claim 9, Hole et al. disclose that there is a control unit 1 within the gas delivery unit 1. Said control unit is connected to said at least one gas sensor 140 and controls flow through the system, meaning that it is capable of switching off the artificial circulation in the event of a blood exchange. See section [0049].

4. With respect to Claim 16, Hole et al. disclose a device 10 comprising a pump arrangement 4, a venous catheter 50 and arterial catheter (14 and 16) for maintaining artificial circulation, a first means 7 for feeding an analysis gas into the artificial circulation, and a second means 140 capable of monitoring whether a blood exchange takes place between the artificial circulation and the systemic circulation of the body 2. Hole et al. further disclose that the first means comprise an oxygenator 32 and an analysis gas delivery line 9 capable of delivering analysis gas into said oxygenator 32, and that the second means comprise at least one gas sensor 140 for the analysis gas. Said at least one sensor 140 is arranged in the artificial circulation.

5. With respect to Claim 26, Hole et al. disclose a blood treatment device comprising an oxygenator 32, an analysis gas delivery line 7, at least one venous catheter (48 and 56), and at least one arterial catheter (14 and 16). See Figures 1 and 9.

6. Claims 1-4, 6, 8-10, 16, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Kamibayashi (US 6,555,058).

7. With respect to Claim 1-4 and 6, Kamibayashi et al. disclose a device comprising a pump arrangement 9, a venous catheter and arterial catheter (4 and 17, respectively) for maintaining artificial circulation, a first means 10 for feeding an analysis gas into the

Art Unit: 3761

artificial circulation, and a second means 30 capable of monitoring whether a blood exchange takes place between the artificial circulation (to the left of dialyzer 11 in Figure 1)) and the systemic circulation of the body 1. Said first means comprises an oxygenator 34 and an analysis gas delivery line 4 through which an analysis gas flows into the artificial circulation. Kamibayashi et al. further disclose that the second means comprise at least one gas sensor 30 for the analysis gas, as per Claim 3. Said at least one sensor 30 is arranged in the artificial circulation, as per Claim 6. See Figures 1 and 9.

8. With respect to Claims 5 and 15, Kamibayashi et al. disclose a device comprising a pump arrangement 9, a venous catheter 17 and arterial catheter 4 for maintaining artificial circulation, a first means 4 capable of feeding an analysis gas into the artificial circulation, and a second means 30 comprising a gas sensor capable of monitoring whether a blood exchange takes place between the artificial circulation and the systemic circulation of the body 2. Kamibayashi et al. further disclose that a further gas sensor is arranged in a respiratory mask 38 and is capable of measuring the air exhaled from the body (column 13, lines 24-42). Therefore, the sensors are capable of detecting the presence of a gas in a patient's breath.

9. With respect to Claims 8 and 10, Kamibayashi et al. disclose a further analysis gas sensor 5 in the analysis gas delivery line 4. Said gas sensor 5 is connected to a control unit 33 which receives data from respective sensors. See Figure 1.

10. With respect to Claim 9, Kamibayashi et al. disclose a control unit is connected to said at least one gas sensor 30 and is capable of controlling flow through the system.

Art Unit: 3761

Therefore, the control unit 33 is capable of switching off the artificial circulation in the event of a blood exchange. See column 12, line 63 through column 13, line 23.

11. With respect to Claim 16, Kamibayashi et al. disclose a device comprising a pump arrangement 9, a venous catheter and arterial catheter (4 and 17, respectively) for maintaining artificial circulation, a first means 10 for feeding an analysis gas into the artificial circulation, and a second means 30 capable of monitoring whether a blood exchange takes place between the artificial circulation and the systemic circulation of the body 1. Said first means comprises an oxygenator 34 and an analysis gas delivery line 4 through which an analysis gas flows into the artificial circulation. Kamibayashi et al. further disclose that the second means comprise at least one gas sensor 30 for the analysis gas, and that said at least one sensor 30 is arranged in the artificial circulation .

12. With respect to Claim 26, Kamibayashi et al. disclose a blood treatment device comprising an oxygenator 34, an analysis gas delivery line 4, a venous catheter 17, and an arterial catheter 4. See Figure 1.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3761

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 5 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hole et al. in view of Burton (WO 01/43804). Hole et al disclose a device comprising a pump arrangement 4, a venous catheter 50 and arterial catheter (14 and 16) for maintaining artificial circulation, a first means 7 capable of feeding an analysis gas into the artificial circulation, and a second means 140 comprising a gas sensor capable of monitoring whether a blood exchange takes place between the artificial circulation and the systemic circulation of the body 2. Hole et al., however, do not disclose that a gas sensor is arranged in a respiratory mask for the air exhaled from the body. Burton

Art Unit: 3761

discloses a respiratory mask comprising sensors capable of detecting the presence of a gas in a patient's breath. It is well known that a gas in the blood stream will eventually be exhaled through the lungs (for example: carbon dioxide). Therefore, the presence of analysis gas in the systemic circulation could easily be detected via a mask placed at the patient's mouth. Therefore, It would have been obvious to one skilled in the art at the time of invention to combine the blood treatment device of Hole et al. with the respiratory gas sensors of Burton in order to determine if the analysis gas is entering the body.

17. Claims 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hole et al. in view of Patterson et al. (US 2003/0095892). Hole et al. disclose a device 10 comprising a pump arrangement 4, a venous catheter 50 and arterial catheter (14 and 16) for maintaining artificial circulation, a first means 7 for feeding an analysis gas into the artificial circulation, and a second means 140 capable of monitoring whether a blood exchange takes place between the artificial circulation and the systemic circulation of the body 2. Hole et al., however, does not disclose that a gas sensor is arranged in the air outlet line of the oxygenator. Patterson et al. disclose a apparatus for blood oxygenation comprising a bulk gas exit vent 64 capable of being controlled by the controller to adjust the air flow rate (Section [0107]). Patterson et al. further disclose that the oxygenator may comprise gas sensors (Section [0117]), which are capable of being arranged in the air outlet line to determine the presence of an analysis gas. It is inherent that a sensor is present in the gas outlet line in order for the controller to achieve the desired air flow rate in the gas outlet line. Therefore, it would have been

Art Unit: 3761

obvious to one skilled in the art at the time of invention to combine the blood treatment device of Hole et al. with the gas sensor of Patterson in order to determine the amount of analysis gas that is exiting the system.

18. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamibayashi et al. in view of Senning et al. (US 3,065,748). Kamibayashi et al. disclose a device comprising a pump arrangement 9, a venous catheter 17 and arterial catheter 4 for maintaining artificial circulation, a first means 4 for feeding an analysis gas into the artificial circulation, and a second means 30 capable of monitoring whether a blood exchange takes place between the artificial circulation and the systemic circulation of the body 1. Hole et al., however, do not disclose that the analysis gas comprises N₂O, nor does he disclose that said at least one gas sensor comprises a N₂O sensor with a sensitivity of 1-1000 ppm. Senning et al. disclose a blood oxygenation device wherein a mixture of oxygen and N₂O are introduced through a tube 16 (column 2, lines 27-29). Regarding the sensitivity of the sensors disclosed in Claims 13 and 14, it is inherent that the sensors are able to record a typical range of concentrations that would be found in an extracorporeal system. It would have been obvious to one skilled in the art at the time of invention to combine the blood treatment device of Hole et al. with the N₂O analysis gas of Senning et al. in order to provide a narcotic that can also be used to determine whether fluid is being transferred into the systemic circulation.

Art Unit: 3761

Conclusion

19. . Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW
11/14/2006

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER
